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Express Mail Label No. **EV 057 398 085 US** Attorney Docket No. 37167-8040.US00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: Johnson *et al.*	EXAMINER: Unknown
SERIAL NO.: 09/916,214	ART UNIT: 3761
FILED: July 25, 2001	CONFIRMATION NO.: 6833

FOR: **APPARATUS FOR DETECTING AND TREATING TUMORS USING LOCALIZED IMPEDANCE MEASUREMENT**

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Prior to examination and calculation of the filing fee of the above-referenced application, please amend the application as follows.

In the claims:

Please cancel claims 1-37, without prejudice.

Please add new claims 38-67 as follows:

38. (New) An apparatus for impedance characterization and ablative treatment of tumors, the apparatus comprising:

an elongated delivery device including a lumen, the elongated delivery device being maneuverable in tissue; and

an impedance array comprising a plurality of resilient members being positionable in the elongated delivery device in a compacted state and deployable with curvature into tissue from the elongated delivery device in a deployed state and defining a sample volume in the deployed state, at least one of the plurality of resilient members including a sensor for determining impedance, at least some of said resilient members being electrodes which can be coupled to an energy source for ablating tissue when electrical energy is supplied to the electrodes from the source, and wherein at least a portion of the resilient members are configured to sample tissue impedance.

39. (New) The apparatus according to claim 38, wherein said impedance characterization is vector impedance characterization and at least a portion of the

impedance array is configured to determine an impedance vector within a selectable tissue site.

40. (New) The apparatus according to claim 38, wherein said impedance characterization is multi-pathway impedance characterization and at least a portion of the impedance array is configured to sample tissue impedance through a plurality of conductive pathways.

41. (New) The apparatus according to claim 40, wherein the plurality of conductive pathways are configured to be substantially evenly distributed or spaced within the sample volume.

42 (New) The apparatus according to claim 38, wherein the plurality of resilient members includes a first, a second and a third resilient member.

43. (New) The apparatus according to claim 38, wherein the sensor has a resistance gradient or a resistance gradient configured to improve determination of a complex impedance.

44. (New) The apparatus according to claim 43, wherein the resistance gradient is along a length of the sensor and configured to compensate for resistive losses or hysteresis along the length of the sensor.

45. (New) The apparatus according to claim 38, wherein at least a portion of the impedance arrays is configured to determine at least one of an intracellular impedance, an interstitial impedance or an intercellular capacitance.

46. (New) The apparatus according to claim 38, wherein the impedance array is configured to determine a locus of impedance within the sample volume.

47. (New) The apparatus according to claim 38, wherein the impedance array is configured to substantially simultaneously determine a first impedance profile at a first

tissue site and second impedance profile at a second tissue site.

48. (New) The apparatus according to claim 47, where, when the impedance characterization is multi-pathway impedance characterization, the first pathway is positioned at a selectable angle relative to the second pathway.

49. (New) The apparatus according to claim 48, wherein the first and second pathway have no common segments.

50. (New) The apparatus according to claim 48, wherein the first and second pathway have a common origin.

51. (New) The apparatus according to claim 50, wherein the first and second pathway have substantially the same pathway, the second pathway being in an opposite direction to the first pathway.

52. (New) The apparatus according to claim 38, wherein the impedance array is configured to detect at least one of an indicator of cell necrosis, a tissue ablation volume, a cell necrosis volume, a tissue thermal volume or a tissue hyperthermic volume.

53. (New) The apparatus according to claim 38, further comprising:

logic resources coupled to at least one of the impedance array, the energy delivery device, the switching device or the energy source, and

a processor operatively coupled to the logic resources.

54. (New) The apparatus according to claim 53, wherein at least one of the impedance array or the logic resources is configured to determine or analyze tissue impedance or complex impedance at a frequency distinct from an ablation frequency.

55. (New) The apparatus according to claim 53, wherein the logic resources are configured to identify a tissue condition or differentiate tissue responsive to an

impedance signal from the impedance array.

56. (New) The apparatus according to claim 53, wherein the logic resources are configured to analyze an impedance signal at a frequency having an increased tissue condition sensitivity relative to a frequency spectrum.

57. (New) The apparatus according to claim 56, wherein the logic resources are configured to distinguish between normal and abnormal tissue, the abnormal tissue including at least one of abnormally mutated tissue, abnormally dividing tissue, cancerous tissue, metastatic tissue or hypoxic tissue.

58. (New) The apparatus according to claim 53, wherein the logic resources are configured to distinguish between necrosed and non-necrosed tissue.

59. (New) The apparatus according to claim 53, wherein the logic resources are configured to identify one of an inflection point, an asymptote, a minimum or a maximum of an impedance signal.

60. (New) The apparatus according to claim 59, wherein the logic resources are configured to identify at least one of an endpoint, an amount of tissue injury or a tissue type utilizing at least one of the inflection point the asymptote, the minimum or the maximum of the impedance signal.

61. (New) The apparatus according to claim 38, wherein the logic resources are configured to identify an endpoint for an ablation procedure responsive to an impedance signal from the impedance array.

62. (New) The apparatus according to claim 38, wherein the impedance signal includes at least one of an intracellular impedance, an interstitial impedance an intercellular capacitance or a complex impedance, and wherein the logic resources are configured to identify a tissue condition utilizing at least one of an impedance ratio including at least one of interstitial to intercellular impedance, real to imaginary

impedance or impedance to capacitance.

63. (New) The apparatus according to claim 55, wherein the impedance signal is a complex impedance and the logic resources are configured to identify a tissue condition of the sample volume utilizing real and imaginary components of the complex impedance signal.

64. (New) The apparatus according to claim 53, wherein the logic resources are configured to compare the impedance of the first tissue site to an impedance of the second tissue site.

65. (New) The apparatus according to claim 39, wherein the impedance array is configured to detect real and imaginary components of the impedance vector or magnitude and phase angle of the impedance vector.

66. (New) The apparatus according to claim 38, further comprising:

an advancement member coupled to the energy delivery device, the advancement member including an actuable portion, the advancement member configured to control deployment of at least a portion of the energy delivery device.

67. (New) The apparatus according to claim 38, wherein at least a portion of the impedance array is configured to sample a complex tissue impedance through a plurality of conductive pathways and detect or measure an indicator of at least one of tumorous tissue or cell necrosis.

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REMARKS

Entry of the amendments prior to examination is respectfully requested.

I. Amendments

Claims 1-37 stand cancelled.

Applicants present claims 38-67 to encompass the subject matter of cancelled claims 1-37 rewritten for clarity and conciseness. Basis for new claims 38-67 is set forth in the following table.

New Claim No.	Basis/Support
38	Original claim 1; page 13, line 19 through page 14, line 4.
39	Original claim 2.
40	Original claims 1 and 8.
41	Original claim 11.
42	Original claim 3.
43	Original claim 4.
44	Original claim 5.
45	Original claim 6.
46	Original claim 7.
47	Original claim 10; page 25, line 20 through page 26, line 8.
48	Original claims 1 and 14.
49	Original claim 15.
50	Original claim 16.
51	Original claim 17.
52	Original claims 18 and 19.
53	Original claim 20.
54	Original claim 21.
55	Original claim 22.
56	Original claim 23.
57	Original claim 24.
58	Original claim 25.
59	Original claim 27.
60	Original claim 28.
61	Original claim 29.
62	Original claim 30.
63	Original claim 31.
64	Original claim 32; page 24, line 13 through page 25, line 5.
65	Original claim 33.
66	Original claim 1.
67	Original claim 35.

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Accordingly, no new matter has been added by way of these amendments.

The Examiner is invited to contact Applicants' representative at (650) 838-4410 if prosecution of this application would be assisted thereby.

Respectfully submitted,

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Date: October 17, 2002

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